



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/576,240

01/19/2007

Iris Meiri-Bendek

7056-X08-021

9083

27317 7590 06/18/2009
Fleit Gibbons Gutman Bongini & Bianco PL
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER

WATTS, JENNA A

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

06/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,240	Applicant(s) MEIRI-BENDEK ET AL.	
	Examiner JENNA A. WATTS	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :20081029, 20090305, 20070119, 20080620, 20081015, 20081015, 20081027.

DETAILED ACTION

Claim Objections

1. Claims 1-6 are objected to because of the following informalities: Claims 1-6 use the phrases "palmitic acid residue" or "palmitic acid moiety"; "fatty acid residue" or "fatty acid moiety"; "glycerol backbone" or "glycerol moiety", interchangeably and for the purposes of clarity, one phrase should be used consistently throughout the claims to describe each of the claimed elements. Appropriate correction is required.
2. Claim 8 is objected to because of the following informalities: Claim 8 appears to be a Markush claim, however, a proper Markush claim should use the phrase "consisting of" prior to the listing of the elements of the group, because the phrase "comprising" allows for other non-claimed elements to also be included. See MPEP 803.02 [R-5]. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1794

5. Regarding Claim 1, in particular, the phrase "characterized in that" is unclear because it is unclear whether the claim limitations following the above phrase are optional or required limitations.

6. Regarding Claims 5, 6 and 11, the phrases "preferably 40-60% w/w", "preferably 6-17% w/w", and "preferably oleic acid", respectively, are unclear because it is unclear whether the limitation following the word "preferably" is an optional or required limitation.

7. Claim 12 is indefinite because the term "optionally" does not serve to further limit Claim 11.

8. Claims 14 and 15 provide for the use of a fat base composition, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 14 and 15 are rejected under 35 U.S.C. 101 because the claimed recitations of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.

Art Unit: 1794

1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-6 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by nutraingredients-usa.com article (published 7/02/03).

13. Enzymotec document is cited as evidence.

14. Regarding Claims 1-6 and 14, the nutraingredients-usa.com article teaches the enzymatically prepared fat base composition called InFat (see article, Page 1, Paragraphs 1-3), which applicant discloses is the fat base composition claimed in Claims 1-6, (see instant specification, Page 11, Paragraph 5, and Page 12, Paragraph 3). Reference is also made to Pages 5-7 of Enzymotec document presented as evidence of the claimed elements of InFat (see Enzymotec InFat information, Pages 5-7). Regarding Claim 14, the nutraingredients-usa.com article also teaches incorporating InFat into infant formulas, (see article, Page 1, Paragraphs 1 and 2), and also teaches that the new ingredient for infant formulas is said to be closer to the fat found in human milk, thus infant formula containing InFat would be deemed a substitute human milk fat composition.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1794

18. Claims 7-10, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over nutraingredients-usa.com article (published 7/02/03) in view of King et al. (U.S. Patent No. 4,876,107).

19. Regarding Claims 7-10, 13 and 15, the nutraingredients-usa.com article is relied upon as cited above in the rejection of Claim 1.

20. Regarding Claims 7-10, the nutraingredients-usa.com article is taken as cited above in the rejection of Claims 1-6 and teaches that the fat base composition known as InFat can be incorporated into infant formulas and the specific composition of InFat makes it more nutritious for infants and also easier to blend with other oils (see article, Page 1, Paragraphs 1 and 2), however the article does not specifically teach blending at least 25% of the fat base composition with up to 75% of at least one vegetable oil, wherein the vegetable oil is one of the claimed oils, and further does not specifically teach infant formula comprising at least one protein component.

21. King teaches a substitute milk fat composition for use in feeding young mammals and especially infants (Column 1, lines 7-8), thus deemed a substitute human milk fat composition and an infant formula, wherein preferably the sn-2 position of the glycerol backbone consists substantially of palmitic acid, particularly 60-90% by weight of the total 2-position fatty acids, and that 1,3-positions include unsaturated fatty acids, preferably largely consisting of oleic and linoleic acids (Column 2, lines 30-33). King teaches that such an arrangement results from the rearrangement of vegetable fat via enzymes (Column 3, lines 20-25). King further teaches that other fats may be included in the composition of the invention, including vegetable oils, for example sunflower oil

Art Unit: 1794

and soya bean oil, having a high content of polyunsaturated fatty acid glycerides, to improve the dietary benefit of the compositions of the invention (Column 2, lines 50-53). King further teaches that the substitute milk fat composition comprises 10-30% vegetable oil, which is below 75%, and the balance of the substitute milk fat composition would be the enzymatically rearranged vegetable fat composition (Column 6, Claims 6 and 8). Therefore, the enzymatically rearranged vegetable fat composition would be present at at least 25% of the substitute milk fat composition. King further teaches that the resulting infant formula provides fat, protein and carbohydrate, where in the fat normally found in such formulations is replaced by an enzymatically rearranged fat in accordance with the present invention (Column 3, lines 20-25). Regarding Claim 10, since vitamins, minerals, nucleotides, amino acids and carbohydrates are optional elements, King is deemed to meet the claimed limitations.

22. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for at least 25% of the enzymatically prepared fat base composition to have been blended with up to 75% of at least one vegetable oil including sunflower or soy oil to provide an infant formula, as taught by King, because King teaches that the addition of vegetable oil to the substitute milk fat composition to prepare an infant formula provides high levels of polyunsaturated fatty acids, along with protein, and improves the dietary benefit of the composition, and further teaches that it is known to prepare infant formulas that comprise a substitute human milk fat compositions with the above claimed ratios of an enzymatically rearranged fat base composition and a vegetable oil. One of ordinary skill in the art would have been motivated by King to add

Art Unit: 1794

up to 75% vegetable oil to a substitute milk fat composition in order to improve the dietary benefits of the composition, thereby ensuring that infants being fed such infant formulas are receiving proper nutrition during feeding.

23. Regarding Claim 13, nutraingredients-usa.com article in view of King are taken as cited above in the rejection of Claim 7 and are deemed to teach a process of preparing the substitute human milk fat composition comprising admixing vegetable oil with the fat base composition (see rejection of Claim 7).

24. Regarding Claim 15, nutraingredients-usa.com article in view of King are taken as cited above in the rejection of Claim 7 and are deemed to teach using the fat composition of Claim 7 in the preparation of an infant formula (see rejection of Claims 7-10).

25. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over nutraingredients-usa.com article, (published 7/02/03) in view of King et al. (U.S. Patent No. 4,876,107), and in further view of Cooper (U.S. Patent No. 5,371,253).

26. Regarding Claims 11 and 12, the nutraingredients-usa.com article is relied upon as cited above in the rejection of Claim 1.

27. Regarding Claims 11 and 12, the article does not specifically teach the process of preparing the fat base composition.

Art Unit: 1794

28. Regarding Claims 11 and 12, King is taken as cited above in the rejection of Claims 1-6 and teaches a process of preparing an enzymatically rearranged fat composition comprising the steps of: (a) reacting an upper-melting fraction of palm oil, which is expected to be rich in palmitic acid, with oleic acid, in the presence of lipase deposited on Celite (Column 4, lines 51-55), which is deemed an insoluble catalyst. It is noted that King also uses hexane in the process, but since Claim 11 claims "comprising the steps of", this does not preclude the use of other elements also present in the process. King further teaches (b) removing the catalyst, and (c) distilling the free fatty acids (Column 4, lines 62-68). Since step (e) is optional, King is deemed to meet the claim limitation. Regarding Claim 12, since the step of fractionation is also optional, King is deemed to meet the claim limitation.

29. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, for the process of preparing a fat base composition to have comprised the claimed steps, as taught by King, because King teaches that such steps result in an enzymatically rearranged substitute human fat milk composition wherein the sn-2 position consists substantially of palmitic acid residues and the sn1- and 3-positions include unsaturated residues and further teaches that such a process is known and one of ordinary skill in the art would have expected a reasonable degree of success in using a known process of preparing an enzymatically rearranged substitute milk fat composition for use in infant formula.

Art Unit: 1794

30. Regarding Claim 11, King does not specifically teach the step (d) of bleaching the oil after distilling.

31. Cooper teaches that processing steps such as bleaching, filtration, deodorization, and the like are techniques known in the art for refining natural vegetable or animal oils and fats and that products produced from fatty acids, such as palm oil or palm kernel oil, can be additionally purified or treated using such techniques (Column 8, lines 64-68, Column 9, lines 1-3 and Column 10, lines 46-47 and 64-66).

32. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, for the process of preparing a fat base composition to have further comprised the step of bleaching, because Cooper teaches that bleaching is one of several techniques known in the art for refining natural vegetable or animal oils and teaches such techniques can be used on products produced from palm oil or palm kernel oil. One of ordinary skill in the art would have been motivated by Cooper to use bleaching as a technique known in the art to refine oils and fats and would have expected a reasonable degree of success in bleaching a fat or oil in order to produce a more refined or treated final product.

Conclusion

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNA A. WATTS whose telephone number is (571) 270-7368. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

Art Unit: 1794

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. W./
J. Watts
Examiner, Art Unit 1794
June 10, 2009

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794